

Applicants : King et al.  
USSN : 10/593,217  
Filed : 9-15-2006  
Examiner : Krishnan Ganapathy  
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Atty. Dkt. No. : 891-A-PCT-US  
Art Unit : 1623  
Date of office action : 5-14-2008  
Date of response : 08-14-2008

#### **REMARKS**

Claims 1-12 and 14-21 are pending in the application. To facilitate the prosecution of the present application claims 1-12 and 14-21 have been canceled without prejudice to Applicants' right to pursue the subject matter in the future, and new claims 34-48 have been added. Support for new claims 34-48 can be found *inter alia* as follows:

New claims	Support
34	Claims 17, 18
35	Claims 17, 18
36, 43	19
37, 44	4
38, 45	5
39, 46	6
40, 47	10
41	11
42, 48	16

Accordingly, Applicants submit that there is no issue of new matters and respectfully request the Examiner to enter the Amendment.

Upon entry, claims 34-48 are pending and under examination in this application.

#### **Rejection Under 35 U.S.C. §112, 1st Paragraph, Enablement**

Claims 17-18 are rejected by the Examiner under 35 U.S.C. §112, 1st paragraph, for lack of enablement. The Examiner contends that the specification, while being enabling for a synergistic combination of VNP40101M with cytarabine (AraC) and

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fludarabine, does not reasonably provide enablement for a synergistic combination of VNP40101M with any other nucleoside. The rejection is respectfully traversed.

Claims 17-18 have been canceled. Applicants submit that claim 34 is drawn to a synergistic combination of VNP40101M with cytarabine, whereas claim 35 is drawn to a synergistic combination of VNP40101M with fludarabine. As indicated in the present specification and acknowledged by the Examiner, Applicants submit that the scope of claims 34-35 is commensurate with the disclosure of the specification, and no undue experimentation is required to practice the invention of claims 34-35.

**Rejection Under 35 U.S.C. §112, Second Paragraph**

Claims 1-12 and 14-21 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The rejection is moot because claims 1-12 and 14-21 have been canceled.

**Rejection Under 35 U.S.C. §103(a)**

Claims 1-12 and 14-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (International J. Toxicology, 21:23-38 (2002)) in view of Gourdeau et al. (U.S. Pat. No. 6,630,480) and Hausheer et al. (U.S. Pat. No. 5,919,816). The rejection is respectfully traversed.

The Examiner contends that Lee et al. teach VNP40101M is a novel alkylating antitumor agent, and acknowledges that Lee et al. do not suggest a combination of VNP40101M with a nucleoside for treatment of tumors. The Examiner contends that Gourdeau et al. teach the use of cytarabine for the treatment of

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leukemia and chronic myelogenous leukemia, and Hausheer et al. teach several classes of antitumor agents including nucleosides that are known to be used for treating tumors.

Applicants submit that claims 1-12 and 14-21 have been canceled. Claims 36 and 43 are drawn to methods of using VNP40101M and cytarabine, or VNP40101M and fludarabine to treat tumor, wherein the use of the two agents together produces a synergistic effect. Applicants submit that the references cited by the Examiner do not teach or suggest a synergistic effect as disclosed and claimed herein. On page 3 of the present office action, it was stated:

The examiner notes that prior art Gourdeau et al. (U.S. 6,630,480) and Hausheer et al. (U.S. 5,919,816) teach the use of nucleosides for the treatment of tumors and leukemias and that they can be combined with other antitumor agents. There is no teaching of potential synergistic combinations comprising nucleosides with other therapeutic agents.

Accordingly, the combined teaching of Lee et al., Gourdeau et al., and Hausheer et al. does not teach each and every aspect of the invention, and the cited references do not render claims 36 and 43 obvious.

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If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicants' undersigned attorney invites the Examiner to telephone him at the number provided below. No fee is deemed necessary in connection with the filing of this response. However, if additional fees are required, authorization is given to charge the amount of any such fee to Deposit Account No. 50-1891.

Respectfully submitted,

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